PETA
PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

HEADQUARTERS
501 FRONT STREET
NORFOLK, VA 23510
TEL 757-622-PETA
FAX 757-622-0457

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Mr. Stephen Johnson, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building, 1101 -A
1200 Pennsylvania Ave., N.W.
Washington, DC 20460

Subject: Public Comments on the HPV Challenge Program Test Plan for the Higher Alkenyl Succinic Anhydride (ASA) Category by Albemarle Corporation.

The following comments on the HPV Challenge Program test plan for the Higher Alkenyl Succinic Anhydride (ASA) Category by Albemarle Corporation are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

The three alkenyl succinic anhydrides comprising the Higher ASA Category are hexadecenylsuccinic anhydride or C16 ASA, octadecenylsuccinic anhydride or C18 ASA and eicosenylsuccinic anhydride or C20 ASA. These differ from each other and from dodecenylsuccinic anhydride, a member of an earlier ASA category sponsored by the Health, Environmental and Regulatory Task Group (HERTG) of the American Chemistry Council (ACC) Petroleum Additives Panel, only in the length of the alkenyl chain attached to the anhydride ring. The major use for the higher ASAs is as an alkaline internal sizing agent for paper. Sizing agents reduce the paper's tendency to be penetrated by water, dyes, and ink, resulting in decreased water absorption and improved print quality.

We commend Albemarle Corporation for its thoughtful use of scientifically appropriate categories of related chemicals as well as existing data for analogous chemicals. The resulting reduction in proposed testing saves animals' lives and is consistent with the HPV Challenge Program's goal of obtaining screening level hazard information.

Albemarle Corporation cites existing data for C1618 ASA for the acute mammalian and acute fish toxicity endpoints. C1618 ASA is described as a commercially available mixture of the C16, C18, and C20 alkenyl substituted succinic anhydrides which comprise the higher ASA category. For the acute mammalian toxicity endpoint, the existing data for C1618 ASA are supplemented by existing data for tetrapropenylsuccinic anhydride and dodecenylsuccinic anhydride, members of the earlier HERTG ASA category. Although Albemarle Corporation notes that HERTG proposed to test tetrapropenyl butanedioic acid for acute fish toxicity, we must reiterate that the log octanol-water partition coefficient (K_{ow}) value of tetrapropenyl butanedioic acid is 4.8 indicating that this

test is inappropriate for the HPV Challenge Program, as stated in EPA's December 2000 *Federal Register* notice (EPA Federal Register, December 2000, p. 81695). Indeed, the major use of the higher ASAs is to render paper more water-repellent. The existing data for C1618 ASA suffices to satisfy the acute fish toxicity endpoint for the higher ASA category.

No existing data were found for repeated dose, reproductive or developmental toxicity endpoints. Albemarle Corporation proposes to review data that will be generated for these endpoints for tetrapropenyl butanedioic acid as part of the earlier HERTG ASA category test plan and to consider whether further testing for the higher ASA category is needed. Once again, while we commend Albemarle Corporation for proposing to satisfy these endpoints by reading across from the closely-related HERTG ASA category, we must reiterate our criticisms of the earlier test plan. In its October 1999 letter to chemical sponsors addressing animal welfare concerns (http://www.epa.gov/chemrtk/ceoltr2.htm), EPA states that participants may conclude that there is sufficient data, given the totality of what is known about a chemical, that certain endpoints need not be tested. The weight of evidence presented in earlier test plans, such as those for Dupont's dicarboxylic acid and ACC's alkaryl sulfonate categories, demonstrates that similar compounds consisting of long alkenyl chains terminated by polar groups tend to have very low overall toxicities. Consistent with this observation, the acute toxicity data for the succinic anhydrides cited in the earlier HERTG ASA test plan and for C1618 ASA are reported as acute oral LD_{50} values in excess of the limit doses of 2000 and 5000 mg/kg, respectively. Furthermore, in the earlier HERTG ASA test plane, ACC proposed to conduct two separate tests to assess repeated dose and reproductive toxicity. While ACC discusses the OECD combined protocol (No. 422) for testing these endpoints, it fails to justify its proposal to use separate protocols that will result in the deaths of twice as many animals. No revisions to this earlier test plan have been posted to date.

In summary, while Albemarle Corporation makes commendable use of categories of related chemicals and existing data for analogous chemicals, thereby reducing testing and saving animals' lives, it proposes to use data generated as part of the earlier HERTG ASA test plan. In reviewing Albemarle Corporation's test plan for the higher ASAs, we urge the EPA to reconsider the inappropriate tests proposed by ACC HERTG in their earlier ASA test plan. Thank you for your attention to these comments. I may be reached at 610-586-3975, or via e-mail at josephm@peta.org.

Sincerely,

Joseph Manuppello
Research Associate
Research & Investigations